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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/697,787 | 10/29/2003 | Nancy Anne Federspiel | AG03-071C | 1171 |

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,787

Applicant(s)

FEDERSPIEL ET AL.

Examiner

Medina A. Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 09/19/05 and 1 nucleic acid encoding SEQ ID NO: 2 in the supplemental response filed 01/23/06 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 are pending.

Claims 4 and 8-10 are withdrawn from consideration as being directed to a non-elected invention.

Claims 1-3 and 5-7 are examined.

Specification

The disclosure is objected to because of the following informalities: for example, page 7, line 9, of the specification contain an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to review the specification for hyperlinks and delete any embedded hyperlink and/or other form of browser- executable code. See MPEP 608.01.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 01/24/05 has been

Art Unit: 1638

considered. However, reference of number 1 listed on page 2 of the IDS form 1449 will not be published on the face of the patent because it cites a hyperlink directed to an Internet address. The use of hyperlinks in the IDS is not allowed under USPTO current policy because the Internet address is subject to a change. It is suggested that the hyperlink be deleted.

Claim Objections

At claim 4, a transgenic plant cannot encode. Appropriate correction is required.

At claim 6, ---transformed--- should be inserted after "A", for clarification.

At claims 6 and 7, it is suggested that "a" be replaced with ---the--- because it refers to a previous claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are indefinite because a nucleotide sequence that is complementary to an encoding nucleotide sequence cannot encode a polypeptide. For example, if SEQ ID NO: 1 encodes a PRDT1 polypeptide, the complementary sequence of SEQ ID NO: 1 cannot encode a polypeptide. Appropriate correction is required to more clearly define the metes and bounds of the claims. Dependent claims 2-3 and 6-7 are included in the rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. The claim does not read, "transformed plant part", therefore the claim reads on the product of nature. Due to chimerism, not all of the parts of a transgenic plant will comprise in their genome the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed plant part, it is unclear whether the claimed plant part would be distinguishable from a naturally occurring plant part. See *Diamond v. Chakrabarty* 447 U.S. 303 (1980, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. Amendment to the claim to read ---transformed plant part--- would obviate the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

Art Unit: 1638

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a transgenic plant comprising a plant transformation vector comprising a nucleotide sequence that encodes or its complementary to a sequence that encodes SEQ ID NO: 2 or an ortholog thereof. The claims are also drawn to a method of increasing a pathogen resistance in a plant by transformation of the plant with a plant transformation vector comprising a sequence or its complementary encoding a PRDT1 polypeptide or an ortholog of SEQ ID NO: 2, a plant produced by said method and plant part thereof.

To satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing (see *vas-Cath*, 935 F.3d at 1563; *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997)).

The *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See, also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from

Art Unit: 1638

that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant describes a transgenic plant comprising a vector comprising a nucleotide sequence encoding SEQ ID NO: 2, and a method of increasing *Peronospora parasitica* disease resistance by introducing into plant/plant cells the nucleic acid sequence of SEQ ID NO: 1, and plants and plant parts produced by said method. Applicant also discloses SEQ ID NO: 2, also from *Arabidopsis*, as being an ortholog of PRDT1.

Applicant has not described the composition or the structure of nucleic acids from various plant and non-plant sources encoding an ortholog of SEQ ID NO: 2, which are all necessary for the production of the claimed transgenic plants/parts and methods. Applicant has not described specific chemical, physical, or any other relevant identifying characteristics that distinguish a nucleic acid encoding a PRDT1 polypeptide from other polypeptides associated with genes that confer resistance against fungal diseases.

While the specification describes EST sequences from *Arabidopsis* as an exemplary PRDT1 polypeptides, the disclosure of the use of a nucleotide sequence encoding SEQ ID NO: 2 does not provide an adequate written description for the nucleic acids as broadly claimed, from any source, including not just plant but non-plant sources. The specification fails to describe structural features common to all nucleic acids encoding a PRDT1 polypeptide that would allow a skilled artisan to predictably determine what will be the identity of the members of the genus. Consequently, the claimed transgenic plants and method that employs a nucleic acid encoding an ortholog

Art Unit: 1638

PRDT1 and transgenic plants comprising said ortholog SEQ ID NO: 2 are not adequately described. Given this lack of written description, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the invention as broadly claimed at the time of filing.

Therefore, weighing all factors above, the claimed invention does not meet the current written description requirements. See, also Written Description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (WO 96/31608).

The claims are broadly drawn to a transgenic plant comprising a plant transformation vector comprising a nucleotide sequence that encodes or its complementary to a sequence that encodes SEQ ID NO: 2 or an ortholog thereof, and a method of increasing a pathogen resistance in a plant by transformation of the plant with a plant transformation vector comprising a sequence or its complementary

Art Unit: 1638

encoding a PRDT1 polypeptide that is an ortholog of SEQ ID NO: 2, a plant produced by said method and plant part thereof.

Jones et al teach a transgenic plant comprising a plant transformation vector comprising a promoter operably linked to a nucleotide sequence encoding a polypeptide that confers resistance to *Peronospora parasitica* designated as RPP5, and a method of transforming a plant with said vector for the production of transgenic plants having increase stress tolerance. Jones et al also teach regenerating a transformed plant from transformed plant cells (see Abstract; page 15, 1st full paragraph; and claims 127-135). Since the polypeptide expressed in the plant is from *Arabidopsis* and having pathogen resistance activity, the prior art polypeptide is considered an ortholog of SEQ ID NO: 2 of the claims, absent evidence to the contrary. The claims do not recite specific structural characteristics that would distinguish the ortholog of the claims from the prior art gene, RPP5. Therefore, Jones et al teach all claim limitations.

Remarks

No claim is allowed.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

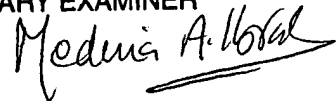
Art Unit: 1638

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

03/30/06

MEDINA A. IBRAHIM
PRIMARY EXAMINER

A handwritten signature in black ink, reading "Medina A. Ibrahim", with a horizontal line underneath.